

# Prehospital Emergency Inguinal Clamp Controls Hemorrhage in Cadaver Model

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**ABSTRACT** Background: The Combat Ready Clamp is indicated to stop difficult inguinal bleeding on the battlefield, the most common type of junctional bleeding and now the most common cause of preventable battlefield death. The purpose of the present study is to report the data of clamp development to help applicers use it correctly. Methods: Wake Forest University investigators used a cadaver model to test the clamp's ability to control hemorrhage. Ten fresh cadavers were made to simulate inguinal and popliteal wound bleeding. Blood simulant was pumped to quantify device effectiveness in testing. Points of application included proximal pressure point control of popliteal, inguinal, and bilateral bleeding. Results: Clamp use promptly controlled pulsing arterial hemorrhages from inguinal, popliteal, and bilateral wounds. The device, when placed on the common iliac artery, stopped all ipsilateral distal bleeding. Conclusions: The evidence of how the clamp works in the cadaver model showed that clamp use can plausibly be tailored to control inguinal hemorrhage from one wound, control two ipsilateral wounds with hemorrhage from one artery (e.g., common iliac artery), and control bilateral inguinal wounds (compression of the origins of bilateral common iliac arteries).

## INTRODUCTION

In the Black Hawk Down battle in Somalia in 1993, a casualty bled to death from an inguinal gunshot wound too proximal for a regular tourniquet—at the limb-trunk junction.<sup>1</sup> Of casualties killed recently in the current war, 20% have had junctional bleeding—now the leading cause of preventable battlefield death—where compression is possible but regular tourniquets cannot fit.<sup>2–8</sup> Junctional hemorrhage control devices such as Lister's tourniquet (also called a clamp) have been used historically and successfully by experts.<sup>9,10,2</sup> Such successes make a clamp plausible for expert medics to control battlefield bleeding from junctional body regions. Similarly constructed devices performed poorly in the past if misplaced, used too long, or were too tight or too loose; but recent evidence of hemorrhage control is that the right device used in the right way at the right time for the right casualty can result in the best practical outcome.<sup>9,11,12</sup>

Hemorrhage can be controlled by direct wound compression for a small, single wound or by compression of a proximal artery for multiple distal wounds.<sup>2</sup> Adequate compression of an artery without collaterals stops blood flow to that artery's bed. The common iliac artery has no effective collateral artery to the lower extremity so that its compression can control flow to its lower extremity.<sup>2,13</sup> Compression of both common iliac

arteries at their one, joined origin can control flow to both lower extremities. In recent studies, artery compression controlled junctional blood flow.<sup>13,14</sup> The Combat Ready Clamp (CRoC) was approved for difficult inguinal bleeds on the battlefield by the U.S. Food and Drug Administration (FDA); the clamp was first fielded to a few troops in 2010. Recently, successful CRoC use for a war casualty was reported, and its technique was described.<sup>15</sup> The purpose of the present study is to report the development of CRoC to increase awareness of the device and the type of injury indicating its use.

## METHODS AND MEASUREMENTS

### *Initial Development of the CRoC*

Using one's hands to maintain pressure directly over a casualty's wound from the point of injury on the battlefield to the emergency department has been impractical; so a device was made to replace the user's manual pressure.<sup>2</sup> In 2009, the U.S. Army Medical Research and Materiel Command posted a request for information for device ideas that could potentially stop bleeding at compressible sites where regular tourniquets could not be applied. To fill this need for a junctional hemorrhage control device, Combat Medical Systems ([CMS] Fayetteville, North Carolina) designed and sponsored a new medical device, the CRoC, which was developed through a cooperative research agreement among CMS, the Wake Forest University School of Medicine Center for Applied Learning, and the U.S. Army Institute of Surgical Research. The CRoC was designed to mechanically compress either a wound or skin and deeper tissues to stop underlying arterial blood flow and wound bleeding internally and externally (Instructions for Use available at <http://www.combatmedicalsystems.com/CRoC-Combat-Ready-Clamp-p/31-200.htm>). The following

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doi: 10.7205/MILMED-D-12-00495

Report Documentation Page				Form Approved OMB No. 0704-0188	
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1. REPORT DATE <b>01 JUL 2013</b>		2. REPORT TYPE <b>N/A</b>		3. DATES COVERED <b>-</b>	
4. TITLE AND SUBTITLE <b>Prehospital Emergency Inguinal Clamp Controls Hemorrhage in Cadaver Model.</b>				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) <b>Kragh Jr. J. F., Murphy C., Steinbaugh J., Dubick M. A., Baer D. G., Johnson J. E., Henkel C. K., Blackbourne L. H.,</b>				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) <b>United States Army Institute of Surgical Research, JBSA Fort Sam Houston, TX</b>				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT <b>Approved for public release, distribution unlimited</b>					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT <b>UU</b>	18. NUMBER OF PAGES <b>7</b>	19a. NAME OF RESPONSIBLE PERSON
a. REPORT <b>unclassified</b>	b. ABSTRACT <b>unclassified</b>	c. THIS PAGE <b>unclassified</b>			

experiments were designed to test the CRoC in controlling hemorrhage from wounds by compressing tissue about the inguinal ligament to report evidence of the 2010 FDA application.

The CRoC was designed analogous to compression devices used in a hospital's catheterization laboratory for femoral artery puncture; e.g., CompressAR Femoral Access Compression Device (Semler Technologies, Portland, Oregon). Such a predicate device externally compresses the femoral artery or vein after transmural catheterization or instrumentation since transmural hemorrhage leads to hematoma complications, including blood loss; device use frees up attendants from manually compressing the wound.<sup>16</sup> The CRoC is made of strong aircraft-grade aluminum, weighs only a pound, and folds flat and small into a medic aid bag (e.g., the common U.S. Army model 9 bag). Medics carry the CRoC preassembled for quick use. The clamp compresses the casualty's tissues and is unattached to things like a litter. When screwed down, it is snugly secure and it has a strap that goes around the casualty's waist to prevent slippage.

In a preparatory trial, a CRoC prototype was checked for fit at anatomic pressure points needed in hemorrhage control. The CRoC was placed on trauma manikins at the U.S. Army Medical Department Center and School by a team that included a hemorrhage control device specialist, a damage control resuscitation expert, and an experienced emergency physician. The prototype fit at the pressure points. The manikins were stiffer than human tissue and were not designed to study pressure point compression or junctional bleeding. Thus, fresh cadavers were sought for evaluations because of the authentic anatomy and tissues, as opposed to manikins or animals.

To assess feasibility, experienced medics from special operation forces took about 10 minutes of CRoC training per medic, which included a couple of practice applications to become proficient. The medics then extensively tested CRoC ruggedness in the field in the dark, rain, snow, and mud; they assessed their own ability to carry the device and to move simulated casualties with the device in use. They fielded the CRoC after its 2010 FDA approval for use on the battlefield to control difficult bleeds in the inguinal area.

### Study Design

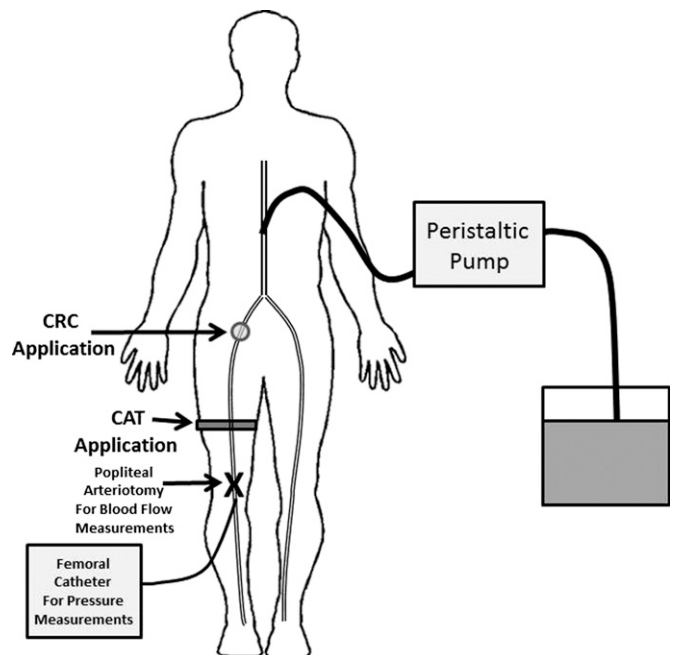
The study design was a sequence of experiments of clamp testing. The three experiments entailed different anatomic sites of clamp placement. To observe the presence or absence of hemorrhage control, a test of one clamp placement at one site was made iteratively. To observe test-retest repeatability, a test was repeated to make a set of four. Ten cadavers were used in testing to observe intersubject variability, and each cadaver underwent the three experiments in order. Tests were made 120 times—4 times in each of the 10 cadavers at three sites. Two of the 10 cadavers were additionally instrumented for arterial pressure measurements. The three clamps used were all of the preproduction prototypes (production lots began with

version A, whereas at this writing version B is in production). A positive control was used to assess model validity.

### Cadaver Model Setup

The human cadaver hemorrhage control model of Wake Forest University Medical Center was used to test the clamp efficacy. Male and female cadavers were used (ages ranged 60–75 years, and weights ranged 110–175 pounds (within military personnel weights)).<sup>17</sup> Donors bequeathed their bodies to the Wake Forest University School of Medicine under the oversight of the school's audit program. The study was conducted under a protocol reviewed and approved by the Wake Forest institutional review board and in accordance with good research practices. The cadavers were refrigerated after death, maintained at a constant temperature above freezing (2°C–3°C), and used within 1 week of death. Cadavers had no surgeries or implants about the areas to be tested.

Cadavers were laid supine on a surgical table (Figs 1–5) and remained at ambient temperature 4 hours before testing. The torso was rotated onto a wood block to intubate the aorta through a left thoracotomy incision. The thoracic aorta was dissected from the posterior mediastinal parietal pleura and the endothoracic fascia (Fig. 3). The aorta was transected so that blood simulant (neutral water with 4% neutral red dye) could be pumped in. Surgical tubing (6-mm internal diameter) from a peristaltic pump (Cole Parmer Masterflex 75553-30) was connected to an endotracheal tube (8-mm internal diameter with rubber piping and plumbing putty as a gasket) inserted 7 cm into the descending thoracic aorta above the diaphragm (Fig. 3). Two 4-inch-long plastic zip ties were placed around



**FIGURE 1.** Schematic of the model used in experiment to test the CRoC's ability to stop wound bleeding. The model was made at Wake Forest University Medical Center.



**FIGURE 2.** Photograph of the model setup in use with simulated blood, buckets, tubes, and pump.

the aorta to hold the tube and gasket in place for a watertight seal. Care was taken not to close the lumen at tie tightening. When intra-arterial blood clots or plaques were large, they were washed out or removed with forceps.

An incision was made through the right vastus medialis muscle to expose the popliteal artery as it emerges at the adductor hiatus—the distal end of Hunter's canal. The popliteal artery was exposed and transected to place a 4-mm surgical tube 3 cm into the proximal end of the artery so that bleeding and measurements of both flow rate and pressure could occur before, during, and after hemorrhage control device use. The tube was held in place and sealed with a 4-inch zip tie overlying the arterial wall. The distal end of the tube went into a 5-gallon bucket to drain, and the bucket was also filled partway with blood simulant as a reservoir for the



**FIGURE 3.** Photograph of the aorta instrumented. Rubber piping as a gasket overlies an endotracheal tube inserted into the descending thoracic aorta. The investigator's gloved finger tips (at the top right of the photograph) retracts tissue.



**FIGURE 4.** Photograph of a right wound in the inguinal and femoral areas. The external iliac and common femoral arteries were exposed, an external iliac arterotomy was made, flow was tested, and the artery was clamped between tests. The proximal scrotum is at the bottom right of the photograph.

pump intake tube. Intra-arterial pressure was monitored by fluid-filled pressure transducers (model 156PC15GWL, Micro-switch, Honeywell Sensing and Control, Morristown, New Jersey powered by a TS430 bridge amplifier [Transonic Systems, Ithaca, New York]) in the distal end of the right femoral artery distal to the device tested. A descending thoracic aorta transducer was placed for proximal measurement. The pump was primed with 30 mL of blood simulant, and the distal arteries were rinsed and flushed with 3 L. The distal artery field



**FIGURE 5.** Photograph of a CRoC placed in use proximal to a right inguinal wound.



was thus filled and pressurized with blood simulant before pump calibration at a pulse rate of 100–120 cycles per minute. End points included measured bleeding rates (wound flow); and aortic and femoral arterial pressure measured before, during, and after device use. Blood pressure data were recorded with IOX2 software (EMKA Technologies, Falls Church, Virginia; Fig. 1). The popliteal artery flow rate was 250–300 mL/min (average 287 mL/min, bleeding at a rate of one unit lost every 94 seconds). The limb artery pulse presence or absence was confirmed by Doppler auscultation (Nicolet Vascular, Imexdop CT + Doppler stethoscope, Golden, Colorado). Femoral artery pressure during popliteal hemorrhage ranged 36 to 48 mm Hg. The popliteal artery was clamped with a surgical hemostat between tests to minimize reservoir loss. Collateral flow absence was monitored for 90 to 180 seconds as the pulse normally returns within 41 seconds.<sup>18</sup>

### **Model Validation: Use of a Regular Limb Tourniquet as a Positive Control**

A Combat Application Tourniquet (C-A-T, sixth generation model, Composite Resources, Rock Hill, South Carolina), currently the most common tourniquet in use today in the U.S. military services, was used on the thigh to check control of hemorrhage from a popliteal wound.<sup>11</sup> The C-A-T was a positive control in the study as a referent hemorrhage control device to assess the model's validity. With a constant blood flow rate equivalent to 1 unit of blood loss every 94 seconds, the C-A-T was applied across the middle of the femoral triangle. After slack was removed from the C-A-T band, three to four windlass turns (540–720° arc) tightened the C-A-T sufficiently to stop wound bleeding similar to use for injured persons and analogous to stopping the distal pulse in normal subjects. Each CAT use controlled hemorrhage had a large arterial pressure drop from proximal to distal at the tourniquet. On CAT release, blood flow and hemorrhage resumed promptly at pre-CAT levels. The results were similar in each of the 10 cadavers tested. CAT use controlled ipsilateral bleeding but did not control contralateral blood flow (pulse or bleeding) as blood flow to the contralateral limb persisted. These findings indicated that the model was valid for device testing as with the CRoC.

## **RESULTS**

### **Experiment 1: Proximal Pressure Point Control of Popliteal Wound Bleeding**

Clamp application in experiment 1 was 1 cm proximal to the inguinal ligament targeting the underlying distal part of the external iliac artery. No inguinal wound was made in experiment 1, but the popliteal wound from the control was used. Hemorrhage, as described in the control after C-A-T release, continued until the CRoC was placed in accordance with the manufacturer's instructions to the cadaver inguinal skin. The clamp was placed where the body armor edge would be and

where a regular tourniquet would not fit. The disk (the half baseball-like part that applies pressure when the skin is being compressed) was halfway between the palpable right anterior superior iliac spine and the right pubic tubercle and 1 cm proximal to the inguinal ligament targeting the distal end of the external iliac artery. The CRoC was put in place so that the pressure disk's hemispheric surface touched the skin tangentially at the disk's pole (center point). Flow pulsated but the average rate was constant before CRoC tightening. The CRoC's handle was turned to tighten the clamp and compress the skin, thereby indirectly compressing the abdominal wall, abdominal contents, and the underlying artery targeted (Instructions for use available at <http://www.combatmedicalsyste.ms.com/CRoC-Combat-Ready-Clamp-p/31-200.htm>). The number of turns of the handle (180° arc was one turn, the supination excursion of the wrist before regripping) for hemorrhage control ranged from four to nine. Cadavers with thicker abdominal fascia required more turns; those with thinner fascia needed fewer. Femoral arterial pressure promptly (<15 seconds) dropped with device use; this duration was the time required to tighten the CRoC by turning the handle. Hemorrhage control and pressure control were concurrent, prompt, and sustained with device use each of the times it was applied for as long as it was used (90–180 seconds). On clamp release, pressure and hemorrhage returned as before clamp use; and reapplication promptly regained hemorrhage and pressure control in all tests. Flow to the contralateral limb persisted as contralateral wound bleeding and pulse persistence with or without clamp use.

### **Experiment 2: Proximal Pressure Point Control of Inguinal Wound Bleeding**

In experiment 2, the clamp was placed 1 cm proximal to the inguinal ligament ipsilateral to the inguinal wound targeting the distal external iliac artery. The compression by the baseball-sized disk was aimed at the midpoint of two adjacent targets. The distal half of the disk compressed the external iliac artery against the deeper bone at the arcuate line of the ilium within the pelvis at its inlet, and the proximal half of the disk compressed the internal iliac artery against the sacral ala (first sacral vertebra's ipsilateral ala). Hemorrhage was controlled as in experiment 1 except that neither collateral flow nor distal wound bleeding nor distal pulse was detected during clamp use; all three were detected between clamp uses. Hemorrhage control was observed with clamp use in all tests, and all clamp releases led to rebleeding. Flow to the contralateral limb persisted as contralateral wound bleeding and pulse persistence with or without clamp use. At clamp release, preclamp pressures returned.

Incremental artery compression with progressive lumen occlusion was evident during successive turns of the handle as flow decreased stepwise at each turn. The first turn had the least hemorrhage control effect on wound bleeding, the effect grew until the penultimate had a major effect, and the final turn stopped all bleeding. In addition, at each pause between

turns as the user regripped the handle, flow rebounded mildly and incompletely. Each successive pause to regrip had a smaller and smaller rebound in flow as the CRoC became tighter and tighter. The flow was stopped for 90 to 180 seconds to assure no collateral flow from the proximal pressure head around the occlusion; similarly, the absence of the pulse distal to the CRoC was monitored to assure no pulse return.<sup>18</sup> No collateral flow was observed from the popliteal artery in all tests with the CRC compressing the distal external iliac artery.

### **Experiment 3: Proximal Pressure Point Control of Bilateral Inguinal Wound Bleeding**

Although clamp application in experiment 2 was proximal to the inguinal ligament, in experiment 3 it was near the umbilicus. CRoC use with the disk application targeting both (i.e., bilateral) origins of the common iliac arteries stopped bleeding simultaneously and promptly from all bilateral limb wounds, inguinal and popliteal. Similarly, the distal pulse in both lower extremities was stopped only when hemorrhage was controlled, and the pulse was only present when hemorrhage was ongoing (such as on clamp release). Hemorrhage control was observed at all wounds in all tests, and no collateral flow was seen on either the left or the right side. At clamp release, preclamp pressures returned. The pump engine strained louder during clamp use in experiment 3 than it did in prior experiments.

Hemorrhage was controlled for the entire duration that the device was used (90–180 seconds) except for one interruption in hemorrhage control, a pressure peak, when the device was intentionally moved and replaced to assess the importance of stabilizing the device and the casualty during transport. Forceful hip abduction or adduction on occasion resulted in device displacement as the pressure disk moved off the artery targeted, and such displacement resulted in prompt pressure changes and rebleeding; other attempts to displace the device by these actions did not result in displacement or bleeding. Accurate replacement restored hemorrhage and pressure control, indicating that users should stabilize both the device and the casualty to minimize slippage during care and transport. After demonstration of no collateral flow, the clamp was released to check the return of flow and pressure. At clamp release, flow rates and pressure returned and stayed at pre-clamp levels (one unit blood lost every 94 seconds at 36–48 mm-Hg). Hemorrhage control was observed in all tests at the popliteal wounds, and flow was also seen from wounds on the contralateral side. Use of the strap in accordance with the instruction sheet prevented or minimized displacement. Accurate placement of the CRoC device on the skin overlaying the external iliac artery was important to device efficacy. Hemorrhage control was variable when the pressure disk was not positioned directly over the external iliac artery. Misplacement led to ineffectiveness as flow and pressure were unchanged from preclamp levels. Accurate placement occurred when the pressure disk's center

point was directly over the underlying artery targeted. Intermediate effectiveness came with near-accurate placement as the pressure disk edge (i.e., equator)—and not its center point (i.e., pole)—was over the artery. Misplacement correction by centering the pressure disk accurately over the external iliac artery resulted in a prompt and sustained reduction in flow and pressure. Such rapid feedback of success (bleeding stopped) and failure (bleeding continued) permitted rapid user learning. With successive trial, error, and correction, user accuracy improved rapidly. At clamp release, preclamp pressures returned.

### **DISCUSSION**

The main finding of the present study is that a prehospital clamp controlled simulated hemorrhage from inguinal wounds in a cadaver model. The CRoC may be used to stop bleeding on the battlefield. The current indication for CRoC is for use in the battlefield to control difficult bleeds in the inguinal area. Such hemorrhage control can be done within a scope of practice as either direct wound compression or proximal artery compression such as at the common iliac artery. Wound compression may work but may require a solitary wound smaller than the disk.

The minor finding of the present study is that when multiple and large wounds occur bilaterally, the device may save lives if it is used at the origin of the common iliac arteries. The medic can tailor device use to compress one common iliac artery for unilateral (ipsilateral) lower extremity hemorrhage or the origin of both common iliac arteries for bilateral injuries. Common iliac artery use may control pelvis, buttocks, external genital, and lower extremity bleeding. Currently, the on-label regulatory indication is for use in the inguinal area. The Black Hawk Down case plainly painted a picture to the regulators of that single need for control of difficult inguinal wound bleeding, but that case was in 1993; and 2011 is different. Such solitary small wounds are rare on today's battlefield. Although the regulatory approval was swift, that labeled indication can save few now. Not only are today's wounds often bilateral, but they are also large, multiple, and in different body regions, including inguinal, gluteal, pelvic, genital, and perineal areas. Compression at the origin of the common iliac arteries showed that the CRoC could control bilateral hemorrhage from multiple wounds. Since the common iliac artery flow goes on to the inguinal, gluteal, pelvic, genital, and perineal areas, the indication need not be constrained unnecessarily in care to inguinal wound bleeding; all these junctional areas are in need of hemorrhage control today. One device may stop bleeding from all these areas at one spot at once. Off-label use of the CRoC can be done for these indications. The compressed targets have anatomic specificity in hemorrhage control and offered therapeutic flexibility in a range of uses. One device is evidently sufficient for bilateral exsanguinating lower extremities (which include the inguinal, gluteal, pelvic, genital, and

perineal areas) instead of two devices. One device at one point at once may control hemorrhage from a right traumatic hip disarticulation, a left gluteal avulsion, a genital injury, and a perineal wound. These are the wound groups that need care today—junctional bleeding in complex groupings. The evidence indicates that a new indication (currently off-label) to use the device at the origins of the common iliac arteries is bilateral junctional bleeding (inguinal, gluteal, pelvic, genital, and perineal areas).

The model explained hemorrhage control for which it was intended. CRoC release promptly restored blood flow completely and arterial pressure to pretest levels, indicating that the devices neither permanently deformed nor blocked arteries; such anatomic and physiologic preservation allowed many repetitions in testing devices. Therefore, the model appears useful and valid for simulating hemorrhage control and for testing devices at physiological rates of bleeding from multiple wounds.

The CRoC acted plausibly as a mechanical compressor of arteries. It specifically compressed the targeted tissues reliably and precisely. It had a safety profile that showed no obvious differences from that of a similar device in a prior study.<sup>14</sup> The analogous historical devices have also shown usefulness in expert hands. The degree of CRoC compression was scalable to the handle turn number, and the hemorrhage control capacity was powerful (unilateral, bilateral, and multiple wounds). Use was focused to specific wound patterns depending on the point of application targeted, and the findings were concordant and not incompatible with established knowledge. Anatomic knowledge and device-specific training evidently are important to best care. The CRoC manikin results are consistent with the cadaver results. These findings associate CRoC use with simulated hemorrhage control when used expertly.

The limitations of the present study are several. Battlefields have no ideal circumstances as opposed to in the experimentally controlled laboratory. The study was of cadaver experiments, not clinical care. The model is purely mechanical, and the blood simulant had no coagulation properties, unlike casualty blood which can clot. The investigators were experts not representative of the average intended user. The experiments were to test a device and were not to elucidate all traits of collateral flow. For example, the device may compress the origins of either or both the internal and external iliac arteries, which may allow or prevent collateral flow. Anatomic verification of the targeted vessel compression or those near the target was not done as with computerized tomography or other imaging. Although the model was used to test a hemorrhage control device for evidencing an FDA application and it explained collateral flow, its primary purpose was to train users; that training was beyond the scope of the present work. Collateral flow was assessed for 90 to 180 seconds; although this may be practical for hemorrhage control, other forms of collateral flow occur beyond this duration.

Furthermore, the pump we used increased aorta pressure at >180 seconds of CRoC use. Such durations led to tube dilation, then bursting; so we thereafter routinely stopped at 180 seconds.

Future research may address these limitations; e.g., a manikin to train CRoC users or testing of the CRoC in the axilla.

## ACKNOWLEDGMENTS

The authors thank LTC Robert Mabry, who assisted with the manikin testing and Otilia Sánchez, who aided in manuscript preparation. Two authors are employees of Wake Forest University. Kragh, Dubick, Baer, Blackburne: internal to U.S. Army Institute of Surgical Research; Steinbaugh: internal to U.S. Army Special Operations Command; Christopher Murphy, internal Combat Medical Systems; James E. Johnson and Craig K. Henkel: internal Wake Forest University Medical Center. A Steinbaugh family member was temporarily a Combat Medical Systems employee. Combat Medical Systems, a company, paid Wake Forest University for study cadavers. Mr. Chris Murphy was an employee of the company that made the inguinal clamp at the time of the development and testing of the device and the writing of the present work. The wife of Mr. John Steinbaugh was an employee of the company for a time during the development and testing of the device.

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